# IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

ONY, INC.,	)
Plaintiff, v.	)
CORNERSTONE THERAPEUTICS, INC., et al.	) Case No. 11-cv-1027-WMS )
Defendants.	) ) )

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS RANGASAMY RAMANATHAN, JATINDER BHATIA, AND KRISHNAMURTHY SEKAR'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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## I. INTRODUCTION

Pursuant to Rules 12(b)(2) and 12(b)(6) of the Federal Rules of Civil Procedure, defendants Rangasamy Ramanathan, Jatinder Bhatia, and Krishnamurthy Sekar (collectively "Defendants") hereby move this Court to dismiss the Complaint in the above-captioned case for lack of personal jurisdiction and failure to state a claim upon which relief can be granted.

In its Complaint, ONY improperly asks this Court to interject itself into the middle of a scientific dispute about the reliability of a peer-reviewed article that analyzed the mortality rates associated with three different drugs that are used to treat premature infants. Many premature infants do not have enough of a material called "surfactant," which lines the surface of the lungs and allows the lungs to function properly. These infants are treated with surfactant drugs to allow their lungs to function until the infants can produce their own surfactants.

Defendant Chiesi Farmaceutici S.p.A. ("Chiesi") and Plaintiff ONY, Inc. ("ONY") are the manufacturers of two of the three animal-derived surfactants that are approved for use in the United States. Defendants are experienced, respected doctors, who work as neonatologists and serve as professors at hospitals and medical schools in California, Georgia, and Oklahoma. Chiesi sponsored an article, authored by Defendants and a clinical researcher, which reviewed the mortality rates associated with use of the three animal-derived surfactants in over 14,000 infants based on data obtained from hospitals around the country. One conclusion of the article was that the mortality rate associated with Chiesi's product was lower than the mortality rate associated with ONY's product. The article was published in the Journal of Perinatology, the official journal of the Section on Perinatal Pediatrics of the American Academy of Pediatrics.

ONY takes issue with the absence of any discussion in the article about the length of stay in the hospital for the infants who were included in the study, alleging that this data is essential to the reliability of the study. ONY advised the Journal of Perinatology and the American

Academy of Pediatrics about its concerns regarding the reliability of the article, and each stood behind the peer-review process and reaffirmed that the article's conclusions reasonably reflected the import of the data. However, ONY remains unsatisfied with the academic medical community's position that the absence of length of stay data in the study does not affect the reliability of the study.

Rather than attempting to resolve this scientific dispute through the standard academic and scientific channels, such as letters by scientists or physicians to a journal concerning a published article, ONY brought this suit. ONY asserted a claim for injurious falsehood against Defendants and also brought claims against Chiesi and its U.S. distributor, the company that supplied the data used in the article, the journal and publishing company, and the American Academy of Pediatrics.

This Court is not the proper venue for this academic dispute. As courts have recognized, a "myriad of problems" would ensue from "judicial forays into the field of scientific research and publication." *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 457 (D.N.J. 2009); *see also Sanderson v. Culligan Int'l*, 415 F.3d 620, 624 (7th Cir. 2005) (finding that the Lanham Act was not "designed to throw into federal courts all disputes about the efficacy of competing products ... and scientific disputes must be resolved by scientific means."). Permitting a party who believes it has been aggrieved by a scientific publication to resolve the dispute through litigation would have a chilling effect on academic speech, the health of which depends upon "that robust exchange of ideas which discovers truth 'out of a multitude of tongues." *Keyishian v. Bd. of Regents*, 385 U.S. 589, 603 (1967). Thus, courts typically avoid entering into scientific debate or taking a position on the validity of scientific theories.

See, e.g., Underwager v. Salter, 22 F.3d 730, 736 (7th Cir. 1994) ("Scientific controversies must

be settled by the methods of science rather than by the methods of litigation."); *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 326 (S.D.N.Y. 2006) ("Courts cannot inquire into the validity of scientific works"); *McMillan v. Togus Reg'l Office, Dep't of Veteran Affairs*, 294 F. Supp. 2d 305, 317 (E.D.N.Y. 2003) ("Any unnecessary intervention by the courts in the complex debate and interplay among scientists that comprises modern science can only distort and confuse."); *Oxycal Labs., Inc. v. Jeffers*, 909 F. Supp. 719, 724 (S.D. Cal. 1995) ("The Court cannot inquire into the validity of [defendant's] scientific theories, nor should it.").

"Scientists should not have to conduct their studies defensively, looking over their shoulders at unnecessary costly litigations." *McMillan*, 294 F. Supp. 2d at 317, 319. ("What is or is not included in the Report goes to the heart of the protections afforded by the First Amendment."); *see also Alacer Corp. v. Nat'l Acad. of Scis.*, Case No. 00CC 10533 (Super. Ct. Calif., Orange County), Order dated January 12, 2001 (dismissing on First Amendment grounds claim based on publication and content of scientific research report that allegedly "failed to include mineral ascorbates in its discussion of Vitamin C"). If courts engaged in such review, every scientific research study could be subject to litigation.

Accordingly, ONY's allegations are not suitable for review by this Court. Additionally, and not surprisingly, given the inappropriateness of a federal court for resolving this dispute, ONY failed to allege the required elements of an injurious falsehood claim. Moreover, the Court should dismiss ONY's claims against Defendants for lack of personal jurisdiction. For these reasons, detailed below, the Court should, therefore, dismiss ONY's claims against Defendants.

## II. STATEMENT OF ALLEGED FACTS

Surfactant drugs are used to treat the lungs of premature infants who suffer from Respiratory Distress Syndrome, which causes difficulty breathing and can be fatal if not treated

effectively. Compl. ¶¶ 17, 18.¹ ONY is the manufacturer of the surfactant drug called Infasurf. Compl. ¶ 20. Chiesi is the manufacturer of the surfactant drug called Curosurf, which Cornerstone Therapeutics, Inc. ("Cornerstone") distributes and markets in the United States. *Id.* ¶ 22.

ONY's Complaint describes an alleged conspiracy led by Chiesi and Cornerstone, who, ONY claims, wanted to publish an article that concluded that preterm infants treated with Curosurf have lower mortality rates than those treated with Infasurf. Compl. ¶ 42. In furtherance of the conspiracy, according to the Complaint, Chiesi paid Drs. Ramanathan, Bhatia, and Sekar to sign their names to and submit for publication an article that compared the mortality rates associated with Infasurf, Curosurf, and Survanta based on data that had been collected from a large number of hospitals (the "Article"). *Id.* ¶¶ 35, 45. *See* Exhibit A to Declaration of J. Kevin Fee ("Fee Decl.").<sup>2</sup> ONY alleges the Article was actually written by agents of Chiesi and Cornerstone. Compl. ¶ 35.

ONY alleges that Chiesi and Cornerstone deliberately omitted data regarding the length of stay ("LOS") in the hospital of the infants who were included in the study. *Id.* ¶ 37, 40.

According to ONY, the reliability of mortality data depends on the inclusion of LOS data. *Id.* ¶ 27. ONY asserts that "[h]ad the Article presented the Curosurf® patients as having both a lower mortality and a shorter length of stay, it would be obvious that the differences in the results were

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Although Defendants dispute many of the factual allegations in the Complaint, they assume that all of the factual allegations are true for the purpose of this motion.

The Article, while not attached as an exhibit to the Complaint, is properly considered on this Motion to Dismiss because it is incorporated by reference into the Complaint (*see*, *e.g.*, Compl. ¶¶ 35-37, 40-42, 49-55). *See Spencer v. Arizona Premium Fin. Co.*, No. 06-CV-160S, 2011 WL 4473178, at \*3 (W.D.N.Y. Sept. 26, 2011) (Skretny, C.J.) (in examining the sufficiency of a complaint on a Rule 12(b)(6) motion to dismiss, the court may consider "any documents that are either incorporated into the complaint by reference or attached to the complaint as exhibits") (quoting *Blue Tree Hotels Inv. (Can.), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 217 (2d Cir. 2004)).

a result of the differences in the groups of patients treated, **not** of any differences in the effect of the particular lung surfactant administered." *Id.* ¶ 67 (emphasis in original).

ONY further alleges that Defendants had access to and were aware of the LOS data, yet chose to omit it from the Article. *Id.* ¶ 41. According to ONY, Defendants knew the content of the Article was deficient, but because they were paid consultants for Chiesi and Cornerstone, they disregarded the alleged deficiencies and submitted the article to the Journal of Perinatology. *Id.* ¶¶ 35, 45. ONY claims that Defendants stood to benefit economically from submitting the Article because the number of articles they publish and the prestige of the journals in which they are published are determining factors in their compensation. *Id.* ¶ 47.

The Article was accepted for publication and published after a peer-review process by the Journal of Perinatology (the "Journal"), which is the official journal of the Section on Perinatal Pediatrics of the American Academy of Pediatrics ("AAP") and which ONY alleges has "considerable clout" in the field. *Id.* ¶ 49, 51, 54, 55, 58, 60. According to the Complaint, ONY advised the Journal and the AAP of its concerns and requested that they retract or denounce the Article, but both have refused to do so. *Id.* ¶¶ 64, 68, 70.

In its Complaint, ONY asserts a claim for injurious falsehood against Defendants, claiming that, as a result of Defendants' submitting the Article that allegedly contained false and unreliable findings to the Journal and misrepresenting the Article to be a result of their own planning, data generation, analysis and writing, ONY lost unspecified sales, the value of its brand has been reduced, and the inherent value of its business decreased by ten percent, including in the amount of \$7.6 million. *Id.* ¶¶ 101, 106. ONY also alleges that its borrowing capacity and its ability to attract capital and talent have decreased as a result of the Article. *Id.* ¶ 106. Therefore, ONY claims damages in an amount to be determined at trial. *Id.* ¶ 107.

## III. ARGUMENT

The Court should dismiss ONY's injurious falsehood claim against Defendants because it does not have personal jurisdiction over any of the Defendants and ONY failed to allege the elements of an injurious falsehood claim under New York law.

#### A. The Court Does Not Have Personal Jurisdiction Over Defendants.

In analyzing a motion under Rule 12(b)(2), a court must first determine whether personal jurisdiction lies pursuant to New York's long-arm statute, CPLR §§ 301 and 302(a). *Nat'l Union Fire Ins. Co. of Pittsburgh. v. BP Amoco P.L.C.*, 319 F. Supp. 2d 352, 357 (S.D.N.Y. 2004) (citing *Omni Capital Int'l Ltd. v. Rudolf Wolff & Co.*, 484 U.S. 97, 105 (1987)). If jurisdiction is found to exist under New York's long-arm statute, the court then addresses whether the exercise of jurisdiction comports with constitutional standards of due process under the Fourteenth Amendment. *Best Van Lines, Inc. v. Walker*, 490 F.3d 239, 241 (2d Cir. 2007).

Under the New York long-arm statute, there are two ways that a New York court can exercise personal jurisdiction over a non-resident defendant: general jurisdiction pursuant to N.Y. CPLR § 301 ("Section 301") or specific jurisdiction pursuant to N.Y. CPLR § 302 ("Section 302").

# 1. The Court Does Not Have General Jurisdiction Over Defendants Under Section 301.

Section 301 provides for jurisdiction over a defendant who is "engaged in such a continuous and systematic course of 'doing business' in New York as to warrant a finding of its 'presence' in the state." *Jazini v. Nissan Motor Co., Ltd.*, 148 F.3d 181, 184 (2d Cir. 1998) (internal quotation marks and citation omitted). An individual "does business" and is therefore "present" in New York and subject to personal jurisdiction with respect to any cause of action if it does business in New York not occasionally or casually, but "with a fair measure of

permanence and continuity." *Wiwa v. Royal Dutch Petroleum Co.*, 226 F.3d 88, 95 (2d Cir. 2000). In determining whether a defendant is subject to general jurisdiction, New York courts look to a number of factors including: (1) the existence of an office in New York; (2) the solicitation of business in the state; (3) and the presence of bank accounts and other property in the state. *Hoffritz for Cutlery, Inc. v. Amajac, Ltd.*, 763 F.2d 55, 58 (2d Cir. 1985).

In the current case, none of the Defendants is engaged in a continuous and systematic course of doing business in New York. Defendants are medical doctors whose business activities focus on treating patients at hospitals that are located outside of New York and conducting research. *See* attached Declaration of Dr. Rangasamy Ramanathan ("Ramanathan Decl.") ¶ 4; Declaration of Dr. Jatinder Bhatia ("Bhatia Decl.") ¶ 4; Declaration of Dr. Krishnamurthy Sekar ("Sekar Decl.") ¶ 4. None of the Defendants has an office in New York. Ramanathan Decl. ¶ 9; Sekar Decl. ¶ 9. None of the Defendants solicits business in New York. Ramanathan Decl. ¶ 13; Bhatia Decl. ¶ 13; Sekar Decl. ¶ 13. None of the Defendants has a bank account or other property in New York. Ramanathan Decl. ¶¶ 10, 14; Bhatia Decl. ¶¶ 10, 14; Sekar Decl. ¶¶ 10, 14. Thus, the court does not have general jurisdiction over Defendants under Section 301.

2. The Court Does Not Have Specific Jurisdiction Over Defendants Under Section 302.

Section 302 provides several avenues for obtaining personal jurisdiction over a non-domiciliary of New York. Defendants are all non-domiciliaries of New York. Ramanathan Decl. ¶ 6; Bhatia Decl. ¶ 6; Sekar Decl. ¶ 6. The Court does not have jurisdiction over Defendants based on any of the provisions of Section 302.

a. The Court Does Not have Jurisdiction Over Defendants Under Sections 302(a)(1), (a)(3)(i), and (a)(4).

A New York court has personal jurisdiction over a defendant who "transacts any business within the state or contracts anywhere to supply goods or services in the state" or who "owns, uses or possesses any real property situated within the state." CPLR § 302(a)(1)&(4). Section 302(a)(3)(i) provides that a New York court will have personal jurisdiction over a non-domiciliary of New York who committed a tortious act outside of New York if he "regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in the state." CPLR § 302(a)(3)(i).

Here, none of the Defendants transacts or solicits business in New York or otherwise engages in any persistent course of conduct in New York. Ramanathan Decl. ¶¶ 8, 13; Bhatia Decl. ¶¶ 8, 13; Sekar Decl. ¶¶ 8, 13. None of the Defendants contracts to supply goods or services in New York; owns, uses, or possesses any real property situated within New York; or derives substantial revenue from goods used or consumed or services rendered in New York. Ramanathan Decl. ¶¶ 12, 14, 16; Bhatia Decl. ¶¶ 12, 14, 16; Sekar Decl. ¶¶ 12, 14, 16. Thus, the court does not have jurisdiction over Defendants based on Sections 302(a)(1), (a)(3)(i), or (a)(4).

b. The Court Does Not Have Jurisdiction Over Defendants Under Section 302(a)(3)(ii) because Section 302(a)(3) Does Not Apply to Claims for Injurious Falsehood, ONY has not Alleged Injury in New York, and Defendants do not Derive Substantial Revenue from Interstate or International Commerce.

The Court does not have jurisdiction over the Defendants under Section 302(a)(3)(ii) because Section 302(a)(3) does not provide for jurisdiction over a non-domiciliary when the cause of action is based on defamation. An injurious falsehood claim sounds in defamation, such that the statutory exception for defamation claims under Sections 302(a)(3) applies. *See Cantor Fitzgerald, L.P. v. Peaslee*, 88 F.3d 152, 157 (2d Cir. 1996) ("Plaintiffs may not evade the

statutory exception [under sections 302(a)(2) and (3)] by recasting their cause of action as something other than defamation.").

Even if Section 302(a)(3) were applicable to a claim for injurious falsehood, the Court would not have jurisdiction over Defendants under Section 302(a)(3)(ii). Section 302(a)(3)(ii) provides that a New York court will have personal jurisdiction over a non-domiciliary who committed a tortious act outside of New York if he "expects or should reasonably expect the act to have consequences in the state and derives substantial revenue from interstate or international commerce." CPLR § 302(a)(3)(ii). The New York Court of Appeals has explained that Section 302(a)(3)(ii) requires a showing that: (1) defendant committed a tortious act outside New York; (2) the cause of action arises from that act; (3) the act caused injury to a person or property within the State; (4) defendant expected or should reasonably have expected the act to have consequences in the State; and (5) defendant derived substantial revenue from interstate or international commerce." *LaMarca v. Pak-Mor Mfg. Co.*, 95 N.Y.2d 210, 214 (2000).

ONY failed to allege that it suffered any injury in New York as a result of Defendants' actions. "It is firmly established that the domicile or residence of an injured party within New York is not enough to establish personal jurisdiction — rather, a more direct injury must have occurred within New York State." *Energy Brands Inc. v. Spiritual Brands. Inc.*, 571 F. Supp. 2d 458, 467 (S.D.N.Y. 2008). Personal jurisdiction must be based upon "a more direct injury within the State and a closer expectation of consequences within the State than the indirect financial loss resulting from the fact that the injured person resides or is domiciled there." *Fantis Foods, Inc. v. Standard Importing Co.*, 49 N.Y.2d 317, 326 (1980). A plaintiff must show harm in the New York market, for example by showing lost sales or customers inside New York. *See id.* at 325-27 & n. 3 (holding that a New York importer did not suffer injury "within the state" when a

non-domiciliary seized a cheese shipment bound for Chicago because there was no allegation of lost sales in New York).

ONY's alleged injury is a general loss of business predicated on Defendants' submission of the Article for publication. ONY does not provide any factual allegations that indicate that it has been injured in New York as a result of Defendants' submission of the Article for publication. It provides general allegations that it lost sales, its business lost value, it has decreased borrowing capacity, and it has a diminished ability to attract capital and talent.

Compl. ¶ 106. Absent from the Complaint is any allegation that ONY lost sales in New York. The fact that ONY is a New York corporation with a principal place of business in New York is insufficient to establish that it has suffered an injury in New York as a result of Defendants' alleged injurious falsehood. *See Fantis Foods*, 49 N.Y.2d at 325-27. As a result, the Court does not have jurisdiction over Defendants under Section 302(a)(3)(ii). *See Pac. Worldwide, Inc. v. Ample Bright Dev., Ltd.*, No. 11-civ-107, 2011 U.S. Dist. LEXIS 143750, at \*8 (S.D.N.Y. Dec. 14, 2011) (dismissing claims for lack of personal jurisdiction where plaintiff did not show any harm in New York resulting from defendants' alleged misrepresentations).

Defendants also do not meet the fifth element of Section 302(a)(3)(ii), which requires a defendant who is a non-domiciliary of New York to derive substantial revenue from interstate or international commerce. This provision of Section 302 is designed to preclude the exercise of jurisdiction over non-domiciliaries whose business operations are "of a local character." *LaMarca*, 95 N.Y.2d at 215. The New York Judicial Conference has described the interstate commerce prong of Section 302(a)(3)(ii) as requiring a showing that defendant "was engaged in extensive business activities on an interstate or international level." 12th Ann. Report of NY Jud. Conf., at 342-343 (cited in *Ingraham v. Carroll*, 90 N.Y.2d 592, 599 (1997)).

In *Ingraham*, the New York Court of Appeals held that a physician who practiced only in Vermont and earned his entire revenue from his local medical services did not derive "substantial interstate revenue" as contemplated by CPLR § 302 (a)(3)(ii). *Ingraham*, 90 N.Y.2d at 600. "Unlike a manufacturer who introduces a product into the stream of commerce expecting it to be sold in other States, a physician treating patients in his or her home State is providing a service that is inherently personal, and local, in nature." *Id.* at 599-600. Similarly, here, Defendants are medical doctors who each derive over 95 percent of their income from their practice of medicine, which is conducted exclusively outside of New York. Ramanathan Decl. ¶¶ 11, 15; Bhatia Decl. ¶¶ 11, 15; Sekar Decl. ¶¶ 11, 15. Defendants simply are not engaged in extensive business activities on an interstate or international level. Ramanathan Decl. ¶¶ 17; Bhatia Decl. ¶¶ 17; Sekar Decl. ¶¶ 17.

As Section 302(a)(3) does not apply to claims that sound in defamation and ONY has not alleged any specific injury in New York and Defendants' business dealings are "of a local character," the Court does not have personal jurisdiction over Defendants under Section 302(a)(3)(ii).

Because the Court does not have jurisdiction over Defendants under New York's longarm statute, it is not necessary to analyze whether the Court's exercise of jurisdiction would comport with the due process requirements under the U.S. Constitution. Whereas the Court has neither general nor specific jurisdiction over Defendants, it should dismiss ONY's claims against Defendants for lack of personal jurisdiction under Rule 12(b)(2).

B. ONY's Claim for Injurious Falsehood Should be Dismissed Because ONY Failed to Allege a Falsehood, Special Damages, or Malice Sufficiently.

In deciding a motion to dismiss under Rule 12(b)(6), the court must "accept . . . all factual allegations in the complaint [as true] and draw . . . all reasonable inferences in the

plaintiff's favor." *Ruotolo v. City of New York*, 514 F.3d 184, 188 (2d Cir. 2008) (internal quotation marks omitted). However, conclusory allegations that merely state the general legal conclusions necessary to prevail on the merits and are unsupported by factual averments should not be accepted as true. *See*, *e.g.*, *New York State Teamsters Council Health and Hosp. Fund v. Centrus Pharmacy Solutions*, 235 F. Supp. 2d 123 (N.D.N.Y. 2002). In order to avoid dismissal, a "complaint must contain sufficient factual matter ... to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (disavowing the statement from *Conley v. Gibson*, 355 U.S. 41 (1957)), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."). The complaint must include sufficient factual allegations "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. As the Supreme Court made clear in *Twombly*, "a formulaic recitation of the elements of a cause of action will not do[.]" *Id*.

Here, ONY's alleges a claim for injurious falsehood (or trade libel), the elements of which are: (i) falsity of the alleged statements; (ii) publication to a third person; (iii) malice; and (iv) special damages. *See Drug Research Corp. v. Curtis Publ'g Co.*, 7 N.Y.2d 435, 440 (N.Y. 1960); *see also Computech Int'l, Inc. v. Compaq Computer Corp.*, 2002 U.S. Dist. LEXIS 20307, No. 02 Civ. 2628, 2002 WL 31398933, at \*5 (S.D.N.Y. Oct. 24, 2002). ONY's claim for injurious falsehood should be dismissed because ONY failed to sufficiently allege a falsehood, special damages, or malice.

## 1. ONY Failed to Allege a Falsehood.

Only assertions of fact, not opinion, can be proven false and are therefore actionable under a claim of injurious falsehood. *Brian v. Richardson*, 87 N.Y.2d 46, 51 (1995). Moreover,

statements of opinion are entitled to absolute protection under the New York Constitution. *Celle v. Filipino Reporter Enters.*, 209 F.3d 163, 178 (2d Cir. 2000); *Immuno AG v. Moor-Jankowski*, 77 N.Y.2d 235 (1991) (expressions of "pure" opinion receive absolute constitutional protection under the New York Constitution). Where "a statement of opinion either discloses the facts on which it is based or does not imply the existence of undisclosed facts, the opinion is not actionable." *Levin v. McPhee*, 119 F.3d 189, 197 (2d Cir. 1997).

Whether a statement is one of fact or opinion is a question of law. *Mann v. Able*, 10 N.Y.3d 271, 276 (2008). Factors to consider in determining whether a statement is opinion or fact include whether it is capable of being proven true or false and whether the context of the communication in which the statement appears signals that the statement is likely to be opinion. *Id.* (quoting *Brian*, 87 N.Y.2d at 51). In assessing the context of a statement, the court must look "at the content of the whole communication, its tone and apparent purpose" to determine whether a reasonable reader would have understood the statement to convey facts, rather than opinion. *Immuno AG*, 77 N.Y.2d at 254 (quoting *Steinhilber v. Alphonse*, 68 N.Y.2d 283, 293 (1986)); *Mann*, 10 N.Y.3d at 276.

The statement challenged by ONY – that preterm infants treated with Curosurf have lower mortality than those treated with Infasurf – is a statement of Defendants' scientific opinions based on their interpretation of data that is fully disclosed in the Article. ONY does not allege that Defendants falsely reported the mortality data underlying the Article's findings. Rather, ONY complains that the ultimate conclusion Defendants drew from that data is invalid because Defendants' methodology did not consider the LOS data. Defendants, respected medical doctors who are experienced in the field of neonatology, were of the opinion that it was not necessary to include or consider the LOS data. One of the peer-reviewers and the editor of

the Journal, the "primary and preeminent publication for practitioners in the field of neonatalperinatal medicine" according to the Complaint, agreed with Defendants' opinion. Compl. ¶¶

39, 49, 50, 51. This dispute is a matter of scientific opinion and is not capable of being
objectively proven as true or false. *See, e.g., Arthur v. Offit,* No. 09-cv-1398, 2010 WL 883745

(E.D. Va. Mar. 10, 2010) (dismissing libel claim regarding plaintiff's views on relationship
between vaccines and autism because the issue was a contentious medical debate and was not an
issue that would be subject to verification.); *Freyd v. Whitfield*, 972 F. Supp. 940, 945 (D. Md.
1997) (defendant's statements on repressed memory at a lecture "cannot objectively be
characterized as true or false.").

Furthermore, even if ONY's opinion is assumed to be correct and reliable conclusions cannot be reached without considering the LOS data, the intended audience of the Article – physicians and other scientists in the field of neonatology – are sophisticated enough to understand that LOS data was not listed among the types of data included in the study and to evaluate the validity of Defendants' findings. The Article clearly discloses the factors that were included in the model to control for potentially confounding variables, which include gestational age, birth weight, gender, race, 3M All Patient Refined Diagnosis Related Group severity of illness category and risk of mortality category. Fee Decl., Ex. A at 2. Thus, the Article itself provides doctors and hospitals with all of the information they need concerning the bases of the study to evaluate whether the Article's conclusions are reliable. As courts have recognized, "a proffered hypothesis that is offered after a full recitation of the facts on which it is based is readily understood by the audience as conjecture." *Gross v. N.Y. Times Co.*, 82 N.Y.2d 146, 154 (1993) (citing *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 28, n.5 (1990) (Brennan, J. dissenting)). Such statements signal to "readers or listeners that what is being read or heard is

likely to be opinion, not fact." *Id.* (quoting *Steinhilber*, 68 N.Y.2d at 292). Thus, the conclusions presented in the Article are statements of scientific opinion and cannot be considered false. *See Brian*, 87 N.Y.2d at 51.

# 2. ONY Failed to Allege Special Damages With Sufficient Specificity.

ONY failed to allege the special damages element of its injurious falsehood claim with specificity, as required by New York law. *See Drug Research*, 7 N.Y.2d at 440 ("[S]pecial damage must be fully and accurately stated."). The requirement of pleading and proving special damages is applied strictly, and a motion to dismiss a claim of injurious falsehood may be granted for failure to allege special damages with the requisite specificity. *See Kasada, Inc. v. Access Capital, Inc.*, No. 01-civ-8893, 2004 U.S. Dist. LEXIS 25257, at \*51 (S.D.N.Y. Dec. 10, 2004) (dismissing plaintiffs' claim for injurious falsehood for failure to state special damages with specificity); *Daniels v. St. Luke's – Roosevelt Hosp. Ctr.*, 2003 U.S. Dist. LEXIS 18772, at \*23 (S.D.N.Y. Oct. 21, 2003).

ONY's Complaint alleges that it suffered lost sales, reduction in worth of the Infasurf brand, diminution in the value of its business in the amount of 10%, decreased capacity to borrow money, and diminished ability to attract capital and employees as a result of Defendants' submission of the Article. Compl. ¶ 81. However, these general, vague allegations of damages are insufficient to meet the requirement of pleading special damages with particularity. *See Nyack Hosp. v Empire Blue Cross & Blue Shield*, 677 N.Y.S.2d 485, 485 (2d Dep't 1998) (holding that plaintiff's general allegations of lost revenues did not satisfy the requirement of pleading special damages with particularity); *LWC Agency, Inc. v. St. Paul Fire & Marine Ins. Co.*, 509 N.Y.S.2d 97, 100 (2d Dep't 1986) ("In pleading special damages, actual losses must be identified and causally related to the alleged tortious act."). For example, "[i]f the special damage alleged is a loss of customers, plaintiff must name the persons who ceased to be

customers, or who refused to purchase its product." *Drug Research*, 7 N.Y.2d at 441 (quoting *Reporters' Assn. of Am. v. Sun Print. & Pub. Assn.*, 186 N.Y. 437, 442 (1906)). ONY failed to name any specific customers it lost or any instance in which it was not able to borrow money or attract capital or employees after the publication of the Article. ONY also failed to allege any facts that support its claim that any such damages were the proximate result of Defendants' submission of the Article or alleged misrepresentations about their role in planning and writing the Article.

In addition, ONY did not provide a specific itemized figure that represents the specific damages it has allegedly suffered as a proximate cause of Defendants' submission of the Article; rather, it simply claims that it has been damaged in an amount to be determined at trial. A claim of damages with no attempt at itemization is insufficient to plead special damages. *Drug Research*, 7 N.Y.2d at 441 (holding that claim of damages in amount of \$5 million with no attempt at itemization was insufficient pleading of special damages); *Kasada*, 2004 U.S. Dist. LEXIS 25257, at \*50-51 (holding that claim of damages "in an amount to be determined at trial but not less than \$40,000,000.00" was insufficient pleading of special damages).

# 3. ONY Did Not Allege Actual Malice Sufficiently.

ONY also failed to allege facts that render plausible the malice element of injurious falsehood. A plaintiff alleging injurious falsehood must plead facts sufficient to allege that defendant acted with actual malice. *See Charles Atlas, Ltd. v. Time-Life Books, Inc.*, 570 F. Supp. 150, 154 (S.D.N.Y. 1983) (citing *Bivas v. State*, 411 N.Y.S.2d 854, 858 (Ct. Cl. 1978) (to support a claim for product disparagement, "malice, comprising either ill will, scienter or deliberate falsification, is necessary"); Restatement (Second) of Torts § 623A, Comment d (1977) ("A principal basis for liability for injurious falsehood [that is, product disparagement] has been that the publisher knew that the statement was false or that he did not have the basis of

knowledge or belief professed by his assertion.")). Actual malice requires proof that the party making the statement had a subjective awareness of either its falsity or probable falsity, or acted with reckless disregard of its truth or falsity. *Celle v. Filipino Reporter Enters. Inc.*, 209 F.3d 163, 182-83 (2d Cir. 2000).

In *Diario El Pais, S.L. v. Nielsen Co.*, No. 07-CV-11295, 2008 U.S. Dist. LEXIS 92987 (S.D.N.Y. Nov. 6, 2008), the plaintiff alleged that defendant published erroneous estimates of the number of visitors to a website. The court found that plaintiff's allegations that defendant knew the estimates were inaccurate were insufficient to meet the pleading requirements for actual malice because the issue of whether the published estimates were accurate came down to a difference of opinion as to which methodology would provide a more accurate estimate. *Id.* at 21. The court held that "contentions that a different methodology would have produced a more accurate result do not amount to allegations that Defendant acted with actual malice when it published results that it had confirmed were consistent with its own methodology." *Id.* at 21-22. Similarly, here, ONY's claims are insufficient to allege actual malice because the Article is unquestionably consistent with the methodology selected by Defendants. ONY's opinion that a different methodology would have been preferable is insufficient to allege actual malice.

As ONY failed to plead sufficiently the elements of falsehood, special damages, and actual malice, the Court should dismiss ONY's claims against Defendants.

## IV. CONCLUSION

For the foregoing reasons, it is respectfully submitted that ONY's claims asserted against Defendants should be dismissed for lack of personal jurisdiction under Rule 12(b)(2) and for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

DATED: January 17, 2012 Respectfully submitted,

## /s/ J. Kevin Fee

J. Kevin Fee

Morgan, Lewis & Bockius LLP

1111 Pennsylvania Avenue, N.W.

Washington, D.C. 20004

202.739.3000

202.739.3001 Facsimile

jkfee@morganlewis.com

Attorney for Defendants Rangasamy Ramanathan, JatinderBhatia, and Krishnamurthy Sekar

# UNITED STATES DISTRICT COURT WESTERN DISTRICT OF NEW YORK

ONY.	INIC
ONI,	IINC

Plaintiff,

V.

CORNERSTONE THEREAPEUTICS, INC., et al.

Case No. 1:11-cv-01027-WMS

Defendants.

## **CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on January 17, 2012, I electronically filed the foregoing Motion to Dismiss by Defendants Rangasamy Ramanathan, Jatinder Bhatia, and Krishnamurthy Sekar with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

Mitchell J. Banas , Jr.
JAECKLE FLEISCHMANN & MUGEL, LLP
Avant Building, Suite 900
200 Delaware Avenue
Buffalo, NY 14202–2107
Counsel for Plaintiff ONY, Inc.

Lauren Erica Handel
McDermott Will & Emery LLP
340 Madison Avenue
New York, NY 10017-4613
Counsel for Defendants Premier, Inc. and Frank R. Ernst

Donall Gerard O'Carroll Nelson Perel Webster Szanyi, LLP 1400 Liberty Building Buffalo, NY 14202 716-842-2800 Counsel for Nature America, Inc. and Edward E. Lawson, M.D.

And, I hereby certify that I have mailed the foregoing, by the United States Postal Service, postage pre-paid, to the following non-CM/ECF participants:

Matthew C. Crowl
SCHIFF HARDIN LLP
233 South Wacker Drive
Suite 6600
Chicago, IL 60606
(312) 258-5500
Counsel for Defendant American Academy of Pediatrics

Robert D. Balin
Davis Wright Tremaine LLP
1633 Broadway
27th Floor
New York, New York 10019-6708
Counsel for Nature America, Inc. and Edward E. Lawson, M.D.

/J. Kevin Fee/